

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Ronald Reagan Building  
International Trade Center  
Horizon Ballroom  
1300 13th Street, N.W.  
Washington, D.C.

**Thursday, April 22, 2004**  
**10:09 a.m.**

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair  
ROBERT D. REISCHAUER, Ph.D., Vice Chair  
SHEILA P. BURKE  
AUTRY O.V. "PETE" DeBUSK  
NANCY-ANN DePARLE  
DAVID F. DURENBERGER  
ALLEN FEEZOR  
RALPH W. MULLER  
ALAN R. NELSON, M.D.  
JOSEPH P. NEWHOUSE, Ph.D.  
CAROL RAPHAEL  
ALICE ROSENBLATT  
JOHN W. ROWE, M.D.  
DAVID A. SMITH  
RAY A. STOWERS, D.O.  
MARY K. WAKEFIELD, Ph.D.  
NICHOLAS J. WOLTER, M.D.

**AGENDA ITEM:**

**Chronic kidney disease and chronic care improvement programs: A case study**

**-- Nancy Ray; Chris Hogan, Direct Research, LLC**

MS. RAY: Good afternoon. Recall that at last month's meeting, Joan, Karen, Rachel and I discussed with you issues associated with implementing the chronic care improvement program, Section 721 of the MMA. Also recall that we will be including this analysis in our June 2004 report. We have revised the chapter to reflect your comments from the March meeting, and please let Sarah Thomas know if you have any additional comments.

In your mailing materials this month we included in the revised chapter a case study on the potential of care coordination services to improve the quality of care for patients with chronic kidney disease. The last portion of the chapter includes the case study, and our objective for today's session is the focus in on this case study.

So let me just go ahead and set some context here. The target conditions set forth by Section 721 are diabetes, congestive heart failure, and chronic obstructive pulmonary disease. Chronic kidney disease patients will most likely be among the participants of this program, at least some of them. Diabetes is the leading cause of renal failure. About 45 percent of incident dialysis patients have diabetes, and about 30 percent have congestive heart failure.

Let me just to say here at this point that CMS's RFP to implement Section 721, however, excludes patients with end-stage renal disease. It does not exclude patients however before they progress to end-stage, so chronic kidney disease patients again will most likely be included among the participants.

This case study discusses some of the issues surrounding chronic kidney disease that policymakers may want to consider when implementing Section 721. So one of the questions that we try to address is, does care coordination have the potential to improve the care for these patients?

The other thing I wanted to mention was, why did we choose chronic kidney disease for our case study? We clearly could have selected other chronic conditions. We selected chronic kidney disease because of the Commission's longstanding interest in improving the quality of care furnished to renal patients.

So let me define up front, what is chronic kidney disease? People generally reach end-stage renal disease as a result of chronic progressive kidney disease. The national Kidney Foundation in their recent guideline defines and divides chronic kidney disease into five stages. That definition was included in the mailing materials. Stage five is permanent renal failure, ESRD. In stage three, the National Kidney Foundation recommends evaluating and treating complications of chronic kidney disease, and in stage four preparing patients for renal replacement therapy.

As I previously said, the underlying disease that cause progressive kidney failure, diabetes and hypertension, at least diabetes is clearly a target conditions and these folks will most likely participate in the program 721.

Why the interest in the potential of care coordination for kidney disease? As the title mentions, Healthy People 2010, one of its objectives is to reduce new cases end-stage renal disease. ESRD, particularly dialysis, is costly. Most patients who are ESRD are on dialysis. There are approximately 300,000 dialysis patients. Patients are hospitalized frequently -- about

twice a year -- and hospitalization and mortality rates have remained high and relatively unchanged during the past decade. ESRD patients fit the profile of groups who might benefit from care coordination as well as chronic kidney disease patients, as I will show you. And finally, ESRD has a negative impact on patients' quality of life.

Our review of the literature suggests that delaying or preventing end-stage renal disease may be possible. It may be accomplished by better care of complications of chronic kidney disease, like anemia, for example. Also, better management of comorbidities like diabetes and hypertension and other cardiovascular conditions.

It's worth pointing out here that patients with chronic kidney disease are more likely to die of cardiovascular causes than to progressed to ESRD. It's also worth mentioning here that there are several programs that do focus on the pre-dialysis population. One in particular is a large HMO in Southern California, and another is actually an alliance, a western New York alliance of insurers and providers. Both programs attempt to identify chronic kidney disease patients when they're in stage three and four and then refer them to a renal team that's composed of nurses, physicians, dietitians and social workers. The focus of the pre-ESRD care is on complications CKD, including anemia, placing vascular, particularly AV fistulas, on proper nutrition, better management of comorbidities, and patient education.

Another reason we are interested in the potential of care coordination is to better prepare - and this is during the pre-ESRD period -- those stage four chronic kidney disease patients who will progress to permanent renal failure. There's some evidence in the literature to suggest that morbidity and mortality of ESRD can be reduced if the comorbidities and underlying causes are better managed.

Again, we're talking about here surgically placing an AV fistula, which takes several months to do so, and providing education about the different renal replacement therapy options, including home dialysis and kidney transplantation.

Your mailing materials reviewed some of the literature that suggests that ESRD morbidity and mortality is reduced for patients who are referred to a renal team earlier. To examine the potential of earlier intervention among chronic kidney disease patients we contracted with Direct Research LLC to follow chronic kidney disease patients in the one year prior and the one year after they first started dialysis. The goal of the study was to look at the use and services and spending based on the timing of the patient's first visit to a provider with expertise in nephrology, and Chris Hogan here will talk about the benefits that he used to do so.

DR. HOGAN: My job was to find these people in the claims and then track their costs and use of services. You have to keep in mind when you look at the results, this is a retrospective study. We started from the first date of dialysis, then we looked backward to the pre-ESRD period, and forward into the ESRD period to track service use and costs.

Probably the most important bullet point on this whole page is the next to the last. Mostly the only people we can find are the elderly, and that's because if you qualify for Medicare services based on ESRD only, you start dialysis before you're on the Medicare program, we can't see your claims. So we had to find people who were already Medicare enrolled and then look at their claims before and after dialysis.

To make this as clean as possible, we took Medicare's official dataset that tracks end-stage renal disease patients and matched it up against the claims to make sure that we agreed with Medicare as to the initial date of dialysis.

So Nancy asked me to look at a few indicators of service, use and quality. Mainly we

wanted to see whether the patient was seen by a nephrologist before the onset of end-stage renal disease, how soon before, how long before, and then what happened prior to and after? Particularly, did they get some kidney disease related treatments prior to the onset of ESRD, and what happened to them after ESRD began.

You have to keep in mind a few things. This is sort of a rough-cut study. We looked for any mention of a physician specialty that being a nephrologist and physician specialty in Medicare is self-reported, so it's self-reporting nephrologist. And if you had even one visit we counted you as having had a consultation with a nephrologist.

We have no way to make this population look like the average incident ESRD patient because all we can do is track the people who were already in Medicare before the onset of ESRD. Probably most importantly, we did no risk adjustment. This is how the claims shake out as you track these people before and after the onset of ESRD. So we didn't look for the comorbidities. And the numbers we show you probably will not match anybody else's numbers because it's a very unusual population in that it's very elderly for an ESRD population. That's the only population for whom we could find claims.

MS. RAY: So Chris classified our study population into four groups based on the number of months between their first visit to a nephrologist and the start of dialysis. Those four groups are, they first saw a nephrologist on or after dialysis, within 4 months before dialysis, between four and 12 months before dialysis, and more than 12 months before dialysis. So when I say late referral patients I typically mean those folks who didn't see a nephrologist until on or after they started dialysis. And the early referral patients are typically those that saw a nephrologist more than 12 months before they started dialysis.

DR. REISCHAUER: Just a question, somebody who's 66 and has first dialysis at age 65 and six months -- you're shaking your head.

DR. HOGAN: Actually, to make it as clean as possible, I required them to have two years of Medicare entitlement prior to the onset of dialysis. So they actually had to be 67 before they started dialysis.

DR. REISCHAUER: Conceivably they could have seen a nephrologist at age 48.

DR. HOGAN: That's correct.

MS. RAY: That's right. This is just in the period before dialysis.

DR. HOGAN: It's really the two years prior to onset. And of course, if they were disabled they could have been younger.

MS. RAY: Right. So I just wanted to reiterate what Chris had said, that the results that we are going to present to you are not representative of all incident dialysis patients because of the selection methods that we used. Our study population is older on average than all incident patients.

Second, as Chris also pointed out, these results are not adjusted for potential differences in demographic and clinical characteristics between our four groups.

So this pie chart shows you that 40 percent of all patients saw a nephrologist more than 12 months before they started dialysis. That's the good news. The not so great news is that 45 percent did not see a nephrologist until four months before dialysis onset.

Chris also looked at when a patient first had a claim for chronic kidney disease; that is, ICD-9-585, which is chronic renal failure. 51 percent had a claim with that diagnosis code more than 12 months before the start of dialysis, and 18 percent had such a claim four to 12 months before the start of dialysis, and 28 percent had a claim one day to four months before the start of

dialysis.

Finally, another interesting piece of information I'd like to mention that Chris just ran out for us is the diagnosis of chronic kidney disease overall among the Medicare beneficiaries. What Chris did was he identified patients with at least two claims for that ICD-9 of 585 which we are using as a proxy for chronic kidney disease, in a given year. So that diagnosis has increased from 0.9 percent in 1996 to 1.6 percent in 2002.

Why is it increasing? The incidence of ESRD is increasing somewhat. And it could also be due to the increased awareness of chronic kidney disease.

DR. ROWE: Is that age adjusted?

MS. RAY: No.

DR. HOGAN: But it's a relatively short time period.

MS. RAY: This is '96 to 2002.

DR. ROWE: The average age of Medicare beneficiaries --

DR. HOGAN: Crept up a bit, but not very much over that period.

MS. RAY: Some moving along to looking at the use of services and outcomes of the study population. In this table of contrasted service use and outcomes for the early referral patients, those who saw a nephrologist more than 12 months before dialysis and the late referral, those whose saw a nephrologist on or after the start of dialysis. You will stay differences in the proportion of patients who received at least one medication for chronic kidney disease complications like anemia or bone disease. This would be an injectable medication. So it would be erythropoietin, for example, for anemia.

Rates of hospitalization in the one month before dialysis are high for both groups, but yet again are less for early referral patients. Use of AV fistula at least one month before dialysis is 30 percent for the early referral versus 10 percent for the late referral patients. Finally, there was a modest difference in mortality one year after dialysis, 25 percent versus 30 percent.

Turning our thoughts to spending, we do find modest differences in spending, \$32,000 for late referral patients versus \$27,000, and that was spent in the year prior to dialysis. Again, there is approximately a \$5,000 difference in the one-year after dialysis between these two groups. You'll note that most of the difference in the one year before dialysis stems from the inpatient spending. Again that tracks back to the previous chart on the rates of hospitalization in the one month before dialysis.

Now this is spending for our entire study population. This tracks spending on a monthly basis. So minus 12 is the twelfth month before dialysis, and plus 12 is 12 months after dialysis. The minus one is that one month before dialysis. You will see that spending peaks in that month. When you look at this same bar chart, separating out the early versus late referral patients, the biggest difference you will see is in the month prior to dialysis, particularly the inpatient spending.

So there's no surprise here that spending goes up once they become dialysis, and we've already spoken about the spike in inpatient costs in the one month prior to them becoming end-stage renal disease. So then at issue here is the potential of care coordination programs to reduce the hospitalization rate before and even after dialysis, and the impact on spending after the program fees would be included in the analysis.

So let me make just a couple of brief conclusions. The literature suggests that earlier intervention and the better management of patients with chronic kidney disease may in some cases delay or prevent ESRD. Our results showed that -- again, our results are not representative

of all incident dialysis patients -- but earlier referral of CKD patients to a nephrologist may reduce the morbidity and mortality associated with ESRD. Care coordination programs as configured under the law may provide opportunities to promote earlier intervention and improve management of stage three and stage four chronic kidney disease.

Next steps that we could think of include evaluating how well the contractors of 721 improve the outcomes of patients with chronic kidney disease, and to examine the potential of different care approaches to improve the quality of care for these patients.

We'd be happy to take comments about this topic.

DR. REISCHAUER: This is going to sound a little gory. When we are comparing the costs, I'm wondering should you take out the cost associated with the people who died? The point is, if you looked at this over two years and you kept the panel the same then they would have zero cost in year two and that's not the way one wants to look at whether Medicare is getting a benefit or not from this. But if you think there's the last year of life problem and every Medicare beneficiary is going to face it sometime. Chris, you've probably thought about this a lot more than I have.

DR. HOGAN: I can offer some comments. One, of all the Medicare beneficiaries with high end-of-life cost, ESRD patients have the highest. They almost always die in the hospital, so end-of-life costs are very important for this population. My second thought was, the elderly ESRD patients have an astronomical mortality rate, 30 percent a year die in this population. The average for all ESRD is about 17 percent, and the younger ESRD is about 12 percent. So to have struck the elderly who died from the cost series entirely -- once they die we don't count them in the denominator anymore, so we don't let the average cost trail off with a bunch of zeroes on the end. We do take the months post-death out of the denominator when we calculate our rates.

But it seemed like such an important component of cost that it was a judgment call to leave them in, but it seemed like a reasonable judgment call to leave them in. We could certainly rerun the numbers, exclude the decedents. You'll see a lot lower series, but I'm not sure that that's the more relevant series.

DR. ROWE: A couple questions. I think this is great that we're doing this, obviously. Why didn't you include transplant? The really elegant way to handle these patients is never to have them dialyzed but to have them go right into a transplant, if they're seen well enough ahead of time and get the work -- so I'm talking about patients who were transplanted but never dialyzed.

DR. HOGAN: Never came up.

DR. ROWE: Because that's really the way to do it. You have a family member who wants to donate. The patient's renal failure is getting worse. Dialysis is terrible, so you transplant the patient.

MS. RAY: I had considered that, and we can certainly do that.

DR. ROWE: Good; thank you.

MS. RAY: But we did put in rates of peritoneal dialysis, and you'll notice with those rates of peritoneal dialysis how much lower they are than all incident dialysis patients, again because of the age of our population. We're dealing with folks who are much older on average than your incident population, so rates of kidney transplantation will be even lower among our study population. That was my one thought of why I did not choose to do that, but we certainly can. It's worth looking at.

DR. ROWE: If you're looking at care management, I think that whether they were seen

by a nutritionist, which there should be a claim for, would be a good measure.

DR. HOGAN: That benefit only got covered recently. So it's such a long time series to pool enough people to find --

DR. ROWE: But if you an epoch of the data in which it's covered, because the thing that the nephrologist does, after confirming that you have chronic kidney disease, is send you to a nutritionist so that you can start to get on the right diet, which is really what it's all about, and then controlling your blood pressure obviously. So that would be a nice marker.

The third is, I think one problem with the logic here, and you're very smart and I'm probably wrong here but that's okay, I'm not easily embarrassed. You noticed that 25 percent mortality in the year after dialysis started in the ones that had been seen by a nephrologist and a 30 percent in the ones that hadn't, and you come up with a statement that says there may be a benefit to mortality. But let me see if I got this right. If you see a nephrologist early then you're likely to be put on dialysis earlier. That is, if you didn't see a nephrologist until the time that you start dialysis or afterward, I bet your creatinine is higher when you're starting on dialysis than if you had seen a nephrologist a year or two ahead of time and they were watching and waiting.

If it's year after the start of dialysis and dialysis is beginning earlier, then you would expect a lower mortality rate in that first 12 months because the people aren't as far advanced and as sick. So there's something wrong with my logic and you tell me what it is.

DR. HOGAN: I'm absolutely amazed that we have numbers that show that it's much better to be referred to a nephrologist and you're disagreeing with us.

DR. ROWE: I'm an insurance salesman. I used to be a nephrologist.

[Laughter.]

DR. HOGAN: But the logic is it is very difficult to draw a causal inference out of --

DR. ROWE: If you have the serum creatinine values, I would bet that the serum creatinine at the outset of the dialysis under people who saw a nephrologist ahead of time is lower. So I would take this statement out about the mortality. I don't think you can say anything about mortality.

DR. HOGAN: This is as another tough call methodologically because it was a retrospective study. Your point is well taken. We took a crack at finding all the CKD patients and then thinking of running -- at least to find the prevalence and running forward to see what happened to them. That would be a different study to do that.

We also took just an informal look at not risk adjustment, per se, but looking at a lot of values for the patients who saw the specialists and who didn't and it looked like the specialist was seeing the sicker patients. So perhaps we could resolve this with a little more risk adjustment to try and figure out --

DR. ROWE: Up until you do a little more I would stay away from statement, because -- you may be right but we're really not confident that you're right until we do a little more study.

DR. NEWHOUSE: I agree with Jack. I think there's going to be a temptation to interpret it causally if it's out there.

I had a picky, technical comment and a picky, technical question. On the power cancellations, which it looks like Chris did, the picky, technical comment is we should say what the assumption is on type II error, which wasn't there.

DR. HOGAN: Yes, I believe that's correct.

DR. NEWHOUSE: The question is, you show samples that would be needed for inferences in later years, and to do that you need the intertemporal correlation, unless you're just

using the actual year to year spending.

DR. HOGAN: This is such a hard question.

MR. HACKBARTH: I was going to ask you the same thing if Joe didn't.

[Laughter.]

DR. HOGAN: We can go down this path but it leads to all sorts of very difficult --

DR. NEWHOUSE: I know, but it turns out that even seemingly relatively small intertemporal correlations matter a lot for power calculations.

DR. HOGAN: Yes, the power calculation that you saw was one year at a time, period.

DR. NEWHOUSE: That's what I suspected.

DR. HOGAN: It was the simplest possible thing to do. It is not clear how the care coordination demo is going to be evaluated. The potential impact of care coordination on the mortality rate makes it a very difficult thing to evaluate, because if I've suppressed the mortality rate in year one I'm left with --

DR. NEWHOUSE: No, it's not the mortality rate. I'm willing to let you assume that the mortality rate -- maybe I shouldn't. You're saying you don't want to assume the mortality as independent of the rate of spending.

DR. HOGAN: I don't know what to assume, and I've asked a lot of people and I haven't got a good answer.

DR. NEWHOUSE: You can get a number on the intertemporal correlation. That's not hard to do. And you can put that into a power calculation. But then to make sense of it you would need some kind of Independence assumption and that's probably not there. But the number that's here is not right either. Maybe you just don't want to do the downstream, the second year after start, third year after start, numbers.

DR. HOGAN: I'm sorry, tell me why that number is not right.

DR. NEWHOUSE: Because basically observing two people for each of one year is better than observing one person for two years because they're not independent.

DR. HOGAN: Yes, so what I --

DR. NEWHOUSE: And you're observing the same people going forward.

DR. HOGAN: Right. I completely admit to doing the simplest possible thing and to ignoring that. But I never got clear direction even from the Federal Register notice as to whether the evaluation is going to be done on were your costs in year three separate from -- I think I must be misunderstanding what you're asking.

DR. NEWHOUSE: No, I'm assuming that somebody is going to want to know the episode cost.

DR. HOGAN: The cumulative three-year cost is what you would rather have seen?

DR. NEWHOUSE: Yes.

DR. HOGAN: I would love to do that calculation. And you want to see that in the report as opposed to a year at a time?

DR. NEWHOUSE: The one year will be the year at a time, but, yes.

DR. HOGAN: You would like to see the three years cumulative done properly.

DR. NEWHOUSE: Yes, because if you are doing one year at a time on the same people, those calculations are not independent.

DR. HOGAN: Yes. I will take that as the go-ahead and go and do that.

DR. MILLER: Can we get an estimate on how much it's going to cost to find this out?

[Laughter.]

DR. STOWERS: I may be jumping ahead here too, but when we looked at what the cost was for a year and that kind of thing, it seems like to me what we're looking at from a cost standpoint is the cost-effectiveness of chronic care management or chronic disease management. So we've got X number of dollars here, if we take that to the final step what would be the cost that was added on to Medicare if this patient had been in some type of a managed care program or management program or whatever? Because it's the net net that's going to make a difference here at to whether it was a cost effective thing for the Medicare program to do or not.

So I think if we don't take this logic to the next step in this chapter somehow then it's not been much guidance as to whether or not this was a good program to have or not to have. Only from cost, not from quality of care or whatever. But I think we need to somehow make that last step at least in some kind of a discussion that everything you see here in savings is not savings, if in fact they've been in a new added-on expense chronic care program. So we're taking a glance at this chart like we just saved \$5,000 here. But we haven't because we've incurred a new expense by contracting with these individuals or whatever company or management company or whatever.

DR. MILLER: I think I follow your point. We shouldn't be talking about this as clear savings if our hypothesis is that somebody is going to need some kind of management. There's a cost to that.

MS. RAPHAEL: I was wondering how you were going to examine the potential of different care coordination models? Because I think in a way this is a microcosm of a group for whom the now classical disease management will not apply, where you really do need some different models given the complexity of this population. We know that it's not out there. We don't know with the CCIO to what extent we'll really get some of the models, what they're now calling case management models. So I was just wondering what your approach is going to be?

MS. RAY: That's a good question and this is clearly something for the future that we would sit down and think about. As a first step, there are a few programs out there that do focus in on the pre-ESRD population and do provide some care coordination for that population, so would clearly be a first step.

To be honest with you, in my search of the peer-reviewed literature I did not find any studies with any kind of statistical analysis on the pre-ESRD population showing the benefits of such programs. But that will definitely be a challenge.

MR. HACKBARTH: Anyone else?

Okay, thank you very much.